U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

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August 29, 2005

via Certified Mail

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2004D-0333

To Whom It May Concern:

The Consumer Product Safety Commission ("CPSC" or "Commission") staff submits this comment in response to the Food and Drug Administration's ("FDA") July 5, 2005 Federal Register notice (70 Fed. Reg. 38,689 (2005)) on the draft guidance entitled "Emergency Use Authorization of Medical Products" dated June 2005. This comment has been prepared by the CPSC staff, has not been reviewed or approved by the Commission, and may not reflect the views of the Commission.

The draft guidance sets forth policies and procedures regarding issuance of emergency use authorizations for the use of unapproved medical products and unapproved uses of approved medical products, including drugs, in the event of an actual or potential emergency during the period of an emergency declaration. The CPSC staff is interested in this process as it relates to the CPSC's mandate to protect young children from accidental poisonings through enforcing the Poison Prevention Packaging Act, 15 U.S.C. §§ 1471-76 ("PPPA"), and the PPPA regulations at 16 C.F.R. Part 1700.

The PPPA regulations require that prescription drugs intended for oral administration to humans and other drugs containing substances specifically regulated under the PPPA be packaged in special (child-resistant and senior-adult-use-effective) packaging. 16 C.F.R. § 1700.15(b). A PPPA-regulated drug that is packaged in violation of the PPPA is a misbranded drug under the Federal Food, Drug, and Cosmetic Act ("FDCA"). *See* 21 U.S.C. § 352(p). The CPSC enforces FDCA functions that relate to the administration and enforcement of the PPPA. *See* 15 U.S.C. § 2079(a). Moreover, drugs that are dispensed in packages that are not child resistant may expose young children to the risk of accidental poisoning due to ingestion of the drug.

The CPSC staff recognizes that in the event of an emergency declaration, large quantities of drugs may be widely distributed to households across the United States. We share the FDA's goal

2004D-0333

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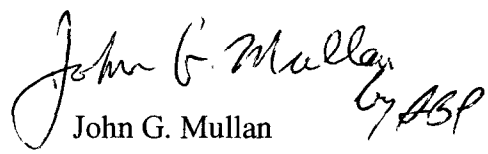
of prompt and efficient widespread drug distribution in a declared emergency, and we fully recognize the priority nature of such a matter. At the same time, we want to bring to the FDA's attention, through this comment, the need to safeguard America's young children from accidental poisonings in the event of such widespread drug distribution.

We applaud your efforts to prepare in advance for such occasions and believe that, through careful planning, child poison prevention and efficient drug distribution can both be accomplished with appropriate use of PPPA-required child-resistant special packaging for drugs. We hope the FDA will take steps to ensure that FDA policies do not give firms the incorrect impression that child-resistant packaging standards would be relaxed for drugs dispensed for household use in an actual or potential emergency. We are happy to assist you in addressing these issues.

Please direct questions regarding this letter to Senior Compliance Officer Geri Smith by telephone at 301-504-7529 or by email at gsmith@cpsc.gov. This comment is based solely on the information currently available to the staff. Additional or new information could change our position and the Commission may supersede the staff position.

Sincerely,



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